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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/353,407	07/15/1999	HELGE LUBENOW	QGN-004.0-US	3483
29425	7590	04/29/2004	EXAMINER	
LEON R. YANKWICH YANKWICH & ASSOCIATES 201 BROADWAY CAMBRIDGE, MA 02139			FREDMAN, JEFFREY NORMAN	
		ART UNIT	PAPER NUMBER	
		1637	22	
DATE MAILED: 04/29/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/353,407	LUBENOW ET AL.
	Examiner Jeffrey Fredman	Art Unit 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 20,25,26,56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 20,25,26,56 and 57 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. ____ .   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____ .                                   |

## DETAILED ACTION

### ***Status***

1. The current application was returned by the BPAI after an affirmance in part decision. The decision indicated that rejections I-IV were affirmed and rejections V and VI were reversed. Claims 1-66 were appealed. So rejections regarding claims 1-19, 21-24, 27-55, 58-66 were affirmed and these claims are closed for further prosecution, in accordance with MPEP 1214.06(III) and the previous grounds of rejection are maintained as affirmed by the BPAI and not appealed to the Federal Circuit.
2. Claims 20, 25, 26, 56 and 57 represent claims which were not in rejections affirmed by the BPAI. These claims will therefore be treated below. In order to simplify prosecution, the claims will be treated as independent and include all the limitations of the broadest independent claim from which they depend for purposes of the prior art rejections.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 20, 25, 26, 56 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiscox et al (Virus Research (1995) 36:119-130).

Hiscox et al teaches a method of separating particles (see page 122, section 2.3) comprising the steps:

a) combining a solution of total cellular RNA with 0.1% SDS with magnetic beads (see page 122, section 2.3, where the magnetic beads meet the particle limitation as shown by claim 13, which specifically claims these as a species of particle),

b) collecting the particles of the particulate matrix material (see page 122, section 2.3, where Hiscox teaches washing of the particles, which inherently requires collection since the particles cannot be washed without collection and separation from the washing buffer),

c) separating the supernatant from the particulate matrix material (see page 122, section 2.3, where Hiscox teaches elution of the RNA, and removal for ethanol precipitation).

With regard to claim 20, Hiscox teaches the use of SDS (see page 122, section 2.3).

With regard to claims 25, 26, 56 and 57, Hiscox teaches a concentration of 0.1% SDS, which falls between 0.05% and 1% (see page 122, section 2.3).

With regard to claims 56 and 57, Hiscox teaches washing, which will disperse the particles, as required by claim 33 (see page 122, section 2.3).

5. Claims 20, 25, 26, 56 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Burg (U.S. Patent 5,780,273).

Burg teaches a method of separating particles (see page 122, section 2.3)

comprising the steps:

- a) combining a solution of DNA targets with a blocking buffer that comprised 0.5% Sarkosyl (see column 16, line 51) with magnetic beads (see column 18, lines 37-52, where the magnetic beads meet the particle limitation as shown by claim 13, which specifically claims these as a species of particle),
- b) collecting the particles of the particulate matrix material (see column 18, lines 48-52, where Burg teaches collection of the ternary complexes),
- c) separating the supernatant from the particulate matrix material (see column 18, line 52, where Burg teaches aspiration of the supernatant).

With regard to claim 20, Burg teaches the use of Sarkosyl (see column 16, line 51).

With regard to claims 25, 26, 56 and 57, Burg teaches a concentration of 0.5% Sarkosyl, which falls between 0.05% and 1% (see column 16, line 51).

With regard to claims 56 and 57, Burg teaches washing, which will disperse the particles, as required by claim 33 (see column 18, lines 53-61).

6. Claims 20, 25, 26, 56 and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Dale et al (U.S. Patent 5,856,092)

Dale et al teaches a method of separating particles (see column 29, lines 19-31) comprising the steps:

- a) combining about 10 microliters of a BSP-1 solution with 100 microliters of a solution comprising 0.1% SDS with magnetic beads (see column 29, lines 20-25, where

the magnetic beads meet the particle limitation as shown by claim 13, which specifically claims these as a species of particle),

- b) collecting the particles of the particulate matrix material (see column 29, lines 26-28, where Dale teaches magnetic concentration of the particles),
- c) separating the supernatant from the particulate matrix material (see column 29, lines 25-26, where Dale teaches removal of the supernatant).

With regard to claim 20, Dale teaches the use of SDS (see column 29, line 22).

With regard to claims 25, 26, 56 and 57, Dale teaches a concentration of about 0.1% SDS, which falls between 0.05% and 1% (see column 28 to column 29).

With regard to claims 56 and 57, Dale teaches washing, which will disperse the particles, as required by claim 33 (see column 29, lines 25-31).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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4/15/04